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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,997	07/26/2001	Donald W. Petersen	06317-038002	1532

26161 7590 09/24/2003

FISH & RICHARDSON PC  
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BOSTON, MA 02110

EXAMINER

WITZ, JEAN C

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/915,997	PETERSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 20, 2003 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 31-42 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-33, 38 and 40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Le.

The phrase "bone graft substitute" is deemed to be a recitation of intended use that fails to confer patentability to an old composition. The patent teaches a composition consisting of calcium sulfate hemihydrate mixed with sterile water optionally containing a thickener such as sodium carboxymethylcellulose. See col. 3, lines 49-51.

Claims 31-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by GB 999,487.

The phrase "bone graft substitute" is deemed to be a recitation of intended use that fails to confer patentability to an old composition. The patent teaches a composition consisting of calcium sulfate hemihydrate mixed with water and methyl sodium carboxymethylcellulose. See Example 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-35, 37 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 999,487.

The patent teaches that the set retardant is a water soluble cellulose ether containing both ionic and non-ionic etherifying substituent groups in the cellulose chain. The ionic substituent may be sodium carboxymethylcellulose and the non-ionic groups may be alkyl, hydroxyalkyl or alkylhydroxyalkyl. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select a conventional cellulose derivatives that fulfill these requirements and therefore act as a set retardant.

Further, it is noted that the amounts of the calcium sulfate hemihydrate in Example 1 and the amount of calcium sulfate hemihydrate recited in claims 41 and 42 are the same and the amount of mixing solution recited in Example 1 falls within the range recited in claim 41. The reference also points out that the "for general purposes the cellulose ether content required will be from 0.1 to 3 per cent of the total weight." Since the reference teaches the desired effect of set retardation and gives a range of desired weight percent, it would have been well within the skill of the practitioner and obvious to one of ordinary skill in the art at the time the invention was made to determine the amounts of plasticizing substance necessary to retard the setting time of the calcium sulfate as desired for any given time frame.

Claims 33-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le.

The patent teaches that the composition may contain a water soluble thickener in an amount sufficient to cause the water component to gel, and suggests, as an exemplary thickener, sodium carboxymethylcellulose. The plasticizing substances recited in claims 33-37 are all well known water soluble thickeners and all but hyaluronic acid are similar in structure and function to sodium carboxymethylcellulose. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select a known water soluble thickener to create a gel with water to mix with the calcium sulfate hemihydrate of the patent.

Further, the patent teaches that the composition is to be sterile and appropriate for pharmaceutical use. Isotonic sterile sodium chloride is often a conventional alternative solvent for pharmaceuticals. Therefore, since all that is required for the solvent of the disclosed mask is that it be of an aqueous nature in order to activate the calcium sulfate hemihydrate, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute sterile isotonic saline for sterile water with the expected result of a calcium sulfate paste that will harden as desired.

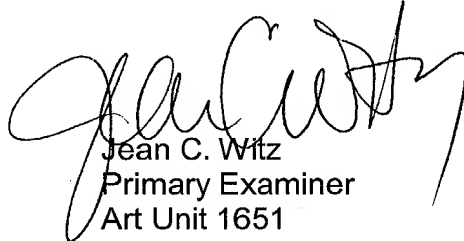
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz  
Primary Examiner  
Art Unit 1651

September 3, 2003